

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 2-18 and 20-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 2-18 and 20-22 recite “an imaging magnetic field with a spatial distribution of the imaging magnetic field strength such that the examination area consists of a first sub-area with lower magnetic field strength and a second sub-area with a higher magnetic field strength”. The present specification does not sufficiently enable a skilled artisan to make and use an examination area consisting of sub-areas with magnetic field strengths. Furthermore, in the event that Applicant intended to claim the sub-areas as "being subjected" to specific magnetic field strengths, the present specification does not sufficiently enable a skilled artisan to vary the imaging field strength. Applicant's attention is directed to page 3, paragraph 1 of the specification, wherein the disclosure describes the gradient field as having sub-areas subjected to different field strengths by way of superimposition of an imaging field and a varying field. Nowhere does the specification describe or illustrate the application of an imaging field with spatially variable strength.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claim 22 is rejected under 35 U.S.C. 102(a) as being anticipated by Applicant's admitted prior art. Applicant admits that the system used to execute the presently claimed method, i.e. a system

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comprising means for executing all steps as set forth in claim 22, was known in the art prior to invention (Specification p. 4 lines 26-27).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2-9, 11-13, 16-18, 22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tournier et al (US PG Pubs. No. 2002/0168321), hereinafter Tournier ('321) in view of Schneider et al (US Patent No. 6,726,650), hereinafter Schneider ('650).

**Regarding claims 2, 4, 5, 7, 22 and 25**, Tournier ('321) teaches an MR system and diagnostic method including means and steps for generating an imaging magnetic field over an examination area such that the area comprises one sub-area subjected to a lower magnetic field strength and a second sub-area subjected to a higher magnetic field strength, acquiring signals that depend on the magnetization in the examination area, and evaluating the signals to determine the spatial distribution of magnetic particles in the examination area (§ 10, 26, 35).

Tournier ('321) does not teach changing the spatial location of the sub-areas, nor does Tournier ('321) teach that the magnetic particles are exposed to a varying magnetic field. In the same field of endeavor, Schneider ('650) teaches subsection of magnetic contrast agents (i.e., magnetic particles) to a varying magnetic field, which is inherently applied in three dimensions and locally restricted, in order to prevent agglomeration of the particles (col. 1 line 60 – col. 2 line 9). Schneider ('650) also teaches that the magnetic field may oscillate, i.e. that the relative position of the examination area should change relative to the magnetic field, also to prevent particle agglomeration (col. 2 lines 5-6). It would have been obvious to one of ordinary skill in the art at the time of invention to have modified Tournier ('321) to include the spatial location changing and varying magnetic field application steps and means of Schneider ('650) and thereby achieve the claimed invention, in view of the teachings of Schneider ('650).

**Regarding claim 3**, Tournier ('321) teaches application of a gradient field (§ 2).

**Regarding claim 6**, Tournier ('321) teaches the particles as having an average size or expansion of at least 30 nm (§ 35).

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**Regarding claims 8, 9 and 12**, neither Tournier ('321) nor Schneider ('650) expressly teach specific values for the varying field strength, power or frequency. However, it would have been obvious to one of ordinary skill in the art at the time of invention to have used a magnetic field of the claimed parameter values, as it has previously been held that, where the general conditions of claim are disclosed in the prior art, discovering the optimum or workable ranges is obvious and unpatentable (*In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)).

**Regarding claim 11**, Tournier ('321) teaches that the particles comprise a magnetic core and nonmagnetic coating (§ 19 and 49).

**Regarding claim 13**, all magnetic fields, including the varying field taught by Schneider ('650), inherently comprise at least one pulse that decays to zero.

**Regarding claim 16**, Schneider ('650) teaches deagglomeration (i.e. application of the varying magnetic field to the particles) prior to administering the magnetic particles to the examination area (col. 1 line 60 – col. 2 line 9).

**Regarding claim 17**, neither Tournier ('321) nor Schneider ('650) teach application of the varying field and, thus, the deagglomeration of the magnetic particles, after the particles are administered to the examination area, or that the varying field is only applied to a part of the examination area. However, one of ordinary skill in the art would have considered it nothing more than an obvious matter of common sense to apply the varying field after administration in order to maximize the effects of deagglomeration during imaging, and to only expose the area to be imaged (i.e., a part of the examination area) to such field, as exposing more of the area would not be useful (*KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385).

**Regarding claim 18**, the obviousness of the claimed frequency range has previously been discussed for claims 8, 9 and 12. Furthermore, a skilled artisan would have considered it nothing more than an obvious matter of common sense to alternate the imaging and varying fields of Tournier ('321) and Schneider ('650), in order to prevent the signal of the varying field from interfering the imaging field (*KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385).

7. Claims 10, 14, 15 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tournier ('321) and Schneider ('650) as applied to claim 2 above, and further in view of Ivkov (US PG Pubs. No. 2006/0142749), hereinafter Ivkov ('749), of record.

Tournier ('321) and Schneider ('650) do not teach the particles to be monodomain particles, nor do they teach that the varying magnetic field is chosen in view of the viscosity of the liquid medium in

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which the particles are dispersed. In the same problem solving area, Ivkov ('749) teaches a method of administering to a patient a solution of magnetic particles wherein monodomain magnetic contrast particles are dispersed in blood, the monodomain particles being configured to be reverse magnetized by Neel rotation, and wherein the frequency of the varying magnetic field is chosen in view of the viscosity of blood (§ 15, 16, 22, 27, 63-64). It would have been obvious to one of ordinary skill in the art at the time of invention to have modified Tournier ('321) and Schneider ('650) to include the steps of Ivkov ('749) and thereby achieve the claimed invention, as such a modification requires nothing more than the mere combination of known prior art steps to yield predictable results, which has previously been held as obvious and unpatentable (*KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385).

8. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tournier ('321) and Schneider ('650) as applied to claim 2 above, and further in view of Rand (US PG Pubs. No. 2005/0066961), hereinafter Rand ('961), of record.

Neither Tournier ('321) nor Schneider ('650) teach the magnetic particle to be a hard or soft multi-domain particle. In the same field of endeavor, Rand ('961) teaches an MR contrast imaging method wherein the magnetic particle is a hard or soft magnetic multi-domain particle. It would have been obvious to one of ordinary skill in the art at the time of invention to have modified the method of Tournier ('321) and Schneider ('650) to employ the particle of Rand ('961), as such a substitution would require nothing more than the mere combination of known prior art elements and steps to yield predictable results, which has previously been held as obvious and unpatentable (*KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385).

### ***Double Patenting***

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 2-18 and 20-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-33 of copending Application No. 10/552,819. Although the conflicting claims are not identical, they are not patentably distinct from each other because they merely claim alternate variations and groupings of the same steps.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 2-18, 20-22 and 25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-33 of copending Application No. 10/552,808. Although the conflicting claims are not identical, they are not patentably distinct from each other because they merely claim alternate variations and groupings of the same steps and elements.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Response to Arguments***

12. Applicant's amendments are sufficient to overcome the previous objections to the drawings and specification, which are hereby vacated accordingly.

13. Applicant's amendments are sufficient to overcome the previous objections to claims 2-18 and 20-22, which are hereby vacated accordingly.

14. Applicant's amendments are sufficient to overcome the previous rejection of claims 4, 7, 8 and 20 under 35 U.S.C. 112, second paragraph, which is hereby vacated accordingly.

15. Regarding the rejection of all pending claims under 35 U.S.C. 112, second paragraph, Applicant argues that, at ages 5 and 6, the disclosure sufficiently describes an imaging field having varying field

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strengths (Remarks p. 12). Examiner first notes that the rejection is predatory on the claim language describing the examination area as having different areas of magnetization; according to the specification, it is not the *area* that has such magnetization, but the *magnetic field* to which the area is subjected that is so varied. Furthermore, pages 5 and 6 of the disclosure describe a magnetic (i.e., gradient) field of varying strength, but fail to set forth an *imaging* field of varying strength. Accordingly, the rejection is proper and is maintained and reiterated herein.

16. Applicant has failed to submit any amendment or argument to overcome the previous rejection of claim 22 under 35 U.S.C. 102(b), which is accordingly maintained and reiterated herein.

17. Regarding the rejection of all pending claims under 35 U.S.C. 103(a), Applicant argues that Tournier ('321) lacks disclosure of generating an imaging magnetic fields with sub-areas having lower and higher magnetic field strength (Remarks p. 14). Examiner maintains that a magnetic field cannot be infinitely homogeneous—it must be stronger closer to the source and weaker further away from the source—and therefore any such field can be said to have "sub-areas" with higher and lower field strengths. Furthermore, Tournier ('321) teaches explicit use of a gradient field in paragraph 2.

Applicant further argues that Schneider ('650) does not disclose changing the spatial location of the and second sub-areas as claimed. Applicant's attention is directed towards col. 1 line 60 – col. 2 line 9 and col. 2 lines 5-6 of Schneider ('650), as noted in the prior Office Action, wherein the reference teaches oscillating a field of varying strength, which Examiner interprets as constituting the changing of the claimed spatial locations.

Applicant also alleges that Schneider ('650) lacks the claimed varying magnetic field (Remarks p. 15). As previously discussed, the reference does in fact meet the limitation.

Applicant further alleges that the Office has failed to provide any motivation to combine the teachings of Tournier ('321) and Schneider ('650) (Remarks p. 15). Applicant's attention is directed towards section 11 of the previous Office Action, which states that "[i]t would have been obvious to one of the ordinary skill in the art [to have combined Tournier ('321) and Schneider ('650)] **in view of the teachings of Schneider ('650)**" (emphasis added) , i.e. that the teaching of Schneider ('650) of performing the reference steps to reduce particle agglomeration would sufficiently motivate a skilled artisan to apply such steps to improve Tournier ('321).

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18. As Applicant has failed to submit a proper terminal disclaimer, the previous double patenting rejection of the claims in view of co-pending application 10/552,808 is maintained and reiterated herein.

### *Conclusion*

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PARIKHA S. MEHTA whose telephone number is (571)272-3248. The examiner can normally be reached on M-F, 8 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571.272.4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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